REMARKS

The Office Action of September 11, 2006, has been received and reviewed.

Claims 1-16 and 18-22 are currently pending and under consideration in the above-referenced application, each standing rejected.

New claims 23-25 have been added.

Reconsideration of the above-referenced application is respectfully requested.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 16 has been rejected under 35 U.S.C. § 112, second paragraph, for reciting subject matter that is purportedly indefinite. Specifically, claim 16 recites administration of a composition including an extract of an avian egg, which is inconsistent with the recitation in independent claim 1 that a composition including a non-avian egg extract is administered to a treated subject.

Independent claim 1 has been amended to remove the requirement that the administered composition include an egg extract from a non-avian source. As such, the subject matter recited in claim 16 is no longer inconsistent with the subject matter of independent claim 1.

Therefore, it is respectfully submitted that claim 16 complies with the definiteness requirement of the second paragraph of 35 U.S.C. § 112, and requested that the 35 U.S.C. § 112, second paragraph, rejection of claim 16 be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-3, 7-13, 15, and 18-22 stand rejected under 35 U.S.C. § 102(b) for reciting subject matter that is allegedly unpatentable over the subject matter described in U.S. Patent 5,367,054 to Lee (hereinafter "Lee").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Lee describes methods for purifying IgY from eggs. The processes that are taught in Lee are useful for obtaining IgY of 90% or greater purity. Lee describes a variety of different processes that may be used in purifying IgY from eggs, setting forth useful combinations of these processes in Fig. 1. The purified IgY of Lee may be used for pharmaceutical purposes or as a health food ingredient. Col. 3, lines 38-40.

Initially, egg yolks are separated from whites, diluted, homogenized, further diluted in a salt-containing buffer, further homogenized, then phase-separated. Col. 5, lines 38-64.

As indicated in Fig. 1 of Lee, phase separation includes separation of an aqueous phase, from which IgY is purified, from a lipid phase, which Lee refers to as a "precipitate phase," from which "phospholipids and other important functional and biologically active components" may be obtained. Fig. 1; col. 5, lines 31-61. As transfer factor is inherently water-soluble, if present, it would initially be present in the dilute aqueous phase, which is subject to further processing to provide a product which is suitable for administration to an animal.

Notably, each of the purification paths shown in Fig. 1 of Lee includes at least one process that would result in the removal of transfer factor and, presumably (*see* final Office Action, page 6), the transfer factor-like component taught in Tokoro. For example, Lee describes an ultrafiltration step, a gel filtration step, and a desalting step.

In the ultrafiltration step, larger molecules, such as antibodies, are separated from smaller molecules, such as transfer factor. Specifically, Lee describes that ultracentrifugation of an aqueous, antibody-containing solution may be effected with a filter having a molecular weight cutoff (MWCO) of either 30,000 Da or 100,000 Da. Col. 5, line 65, to col. 6, line 14. As the MWCO of the ultracentrifugation filter disclosed in Lee is much larger than the molecular weights of transfer factor molecules, which are known to be less than about 10,000 Da, any transfer factor that may have otherwise been present in the purified aqueous, antibody-containing solution would be separated from the larger antibody molecules, which have molecular weights of about 168,000 Da. As a result, the resulting composition, which Lee indicates may subsequently be administered to a mammal, would not include transfer factor.

Lee also describes that ion exchange chromatograpy, including anion exchange chromatography or cation exchange chromatography, may be used to purify IgY. Col. 6, line 15,

to col. 7, line 2. In ion exchange chromatography, the solid phase of the column somewhat selectively binds side chains of the molecule of interest, in this case molecules that are to be removed from the final product. As is well known in the art and suggested in Lee, the binding selectivity of the column must be specifically tailored to capture the molecule(s) of interest. Transfer factor is a hydrophilic, polar molecule. *See* U.S. Patent 5,840,700 to Kirkpatrick et al., col. 2, lines 39-41. Therefore, the highly polar solid phase materials of the types described in Lee would, more likely than not, capture transfer any factor molecules, while IgY readily passes through such a column. *See,* Lee, col. 6, lines 47-55. Therefore, even if present in the eggs of Lee, transfer factor would not necessarily remain in Lee's product following purification with an ion exchange column.

At col. 7, lines 3-15, Lee describes use of precipitation processes in the purification of IgY. The precipitation methods that are described in Lee, which are similar to those described in the '799 Application, result in the precipitation of IgY from solution, while much smaller proteins, such as transfer factor (if even present), remain in solution, which is to be discarded.

Gel filtration, another process that Lee describes may be useful in purifying IgY (col. 7, lines 16-24), is also effected on the basis of molecular weight. Lee describes that the compositions thereof need only include three components: γ-livetin (IgY), α-livetin, and β-livetin. As transfer factor molecules have smaller molecular weights than any of these desired molecules, if they were even present in the eggs of Lee, they would remain trapped in the pores of the gel beads of a gel filtration column longer than any of the desired molecules and, thus, would not be present in the resulting composition.

In the desalting step (col. 7, lines 25-37; col. 12, lines 40-58), which is necessary since the presence of salt (from initial separation) in the purified IgY will adversely affect antigen-binding, the aqueous, antibody-containing solution of Lee is dialyzed. The disclosure of Lee is limited to use of a dialysis membrane that has a MWCO of 12,000 Da to 14,000 Da. As the MWCO of the dialysis membrane taught in Lee is much larger than the molecular weights of transfer factor molecules, any transfer factor that may have otherwise been present in the aqueous, antibody-containing solution would pass through the pores of the dialysis membrane and, thus, be removed from the solution.

Thus, when compositions resulting from the processes of Lee are administered to mammals, they do not include transfer factor.

It is, therefore, respectfully submitted that Lee does not expressly or inherently describe, a method that includes "administering to [a] treated animal a quantity of a composition including an extract . . . comprising transfer factor," as would be required to anticipate the method of independent claim 1, as well as the method of independent claim 20 under 35 U.S.C. § 102(b). Thus, under 35 U.S.C. § 102(b), the subject matter recited in both independent claim 1 and independent claim 20 is allowable over the subject matter described in Lee.

Claims 2, 3, 7-13, 15, 18, 19, and 22 are each allowable, among other reasons, for depending directly or indirectly from claim 1, which is allowable.

Claim 2 is further allowable since it is apparent from the purification techniques described in Lee that all molecules having molecular weights of about 4,000 Da to about 5,000 Da will be removed from the final, useful compositions.

Claims 10, 12, and 13 are each additionally allowable since Lee lacks any express or inherent description of administering a composition that includes transfer factor specific for at least one antigen of a pathogen.

Claim 18 is additionally allowable since Lee does not expressly or inherently describe that non-mammalian transfer factor may be administered to a treated subject.

Claim 19 is further allowable because Lee neither expressly nor inherently describes that, following administration of one of the compositions of Lee to a subject, transfer factor in the composition (there is none) "causes the treated animal, *in vivo,* to elicit [a] T-cell mediated immune response."

Claim 22 is also allowable since Lee includes no express or inherent description of "administering to [a] treated animal a sufficient quantity of [a] composition to enhance an ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response . . ." Rather, the description of Lee is limited to administering compositions that include substantially purified antibodies, which cause the treated subject to elicit a B-cell immune response, not a T-cell mediated immune response.

Claim 21 is allowable, among other reasons, for depending directly from claim 20, which is allowable. Additionally, claim 21 is allowable since it is apparent from the purification techniques described in Lee that all molecules having molecular weights of about 4,000 Da to about 5,000 Da will be removed from the final, useful compositions.

It is respectfully requested that the 35 U.S.C. § 102(b) rejections of claims 1-3, 7-13, 15, and 18-22 be withdrawn, and that each of these claims be allowed.

Rejections under 35 U.S.C. § 103(a)

Claims 4-6 and 14 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is assertedly unpatentable over the subject matter taught in Lee, in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick (hereinafter "Kirkpatrick").

Claims 4-6 and 14 are each allowable, among other reasons, for depending directly from claim 1, which is allowable.

It is also respectfully submitted that the teachings of Lee and Kirkpatrick do not support a *prima facie* case of obviousness against any of claims 4-6 or 14. Specifically, it is respectfully submitted that, without the benefit of hindsight that the claims of the above-referenced application provide to the Office, one of ordinary skill in the art wouldn't have been motivated to combine teachings from Lee and Kirkpatrick in the manner that has been asserted. For example, the teachings of Lee and Kirkpatrick are mutually exclusive. Lee's teachings are limited to methods for purifying antibodies. Such methods exclude a variety of other molecules, including transfer factor molecules, from the resulting compositions. The methods of Kirkpatrick, conversely, are drawn to purifying transfer factor from other molecules, including antibodies.

As such, a *prima facie* case of obviousness has not been established against any of claims 4-6 or 14, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

New Claims

New claims 23-25 have been added.

New claims 23 and 24 depend from independent claim 1. New claim 23 includes substantially the same subject matter as that previously recited in claim 17. New claim 24 recites that the administered composition includes an extract that has been treated to purify transfer factor from other proteins or peptides having molecular weights of greater than about 8,000 Da.

New claim 25 depends from independent claim 20 and recites that the administered composition includes an extract that has been treated to purify transfer factor from other proteins or peptides having molecular weights of greater than about 8,000 Da.

CONCLUSION

It is respectfully submitted that each of claims 1-16 and 18-25 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

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